

# Schedule of Accreditation



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Accreditation Standard	EN ISO 15189
Date of award of accreditation	17/02/2009
Scope Classification	Microbiology and Virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology

Services available to the public<sup>1</sup> Yes

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)

	<b>Name</b>	<b>Address</b>
1	Blackrock Clinic Laboratory	Rock Road, Blackrock, Dublin, Ireland, A94E4X7

# Scope of Accreditation

## Blackrock Clinic Laboratory

### Blood Transfusion Science

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	Blood grouping (ABO & RhD) Typing	Whole blood in EDTA	Grifols DG Gel Card Technology Column agglutination technology	CE./Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Grifols DG Gel Card Automated System Column agglutination technology	CE/ Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	EDTA Plasma	Grifols Manual and Automated Gel Card Systems Column agglutination technology	CE/Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077

1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Grifols Manual and Automated Gel Card Systems Column agglutination technology	CE/ based on standard method	N/A	LM-BT-0019 LP-BT-0047 EXT-BT-0077	
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch testing		Grifols Manual and Automated Gel Card Systems Electronic issue	CE/ based on standard method	N/A	LM-BT-0010 EXT-BT-0055 LP-BT-0047 EXT-BT-0077	
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing		Red Blood Cells	Grifols Manual and Automated Gel Card Systems	CE/ based on standard method	N/A	LM-BT-0018 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .09 Direct antiglobulin test (DAT)	Direct antiglobulin test (DAT)		Red Blood Cells in EDTA	Automated Method using Eflexis Grifols DG Gel Card System  Manual Method using Grifols DG Gel Card System	CE/ based on standard method	N/A	LM-BT-0021 LP-BT-0047 EXT-BT-0077
<i>a. The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)</i>							

## Blackrock Clinic Laboratory

### Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count with automated differential leucocyte count	EDTA Blood	Automated Electrical Impedance VCS technology Calculations	Beckman Coulter Unicel DxH 800	CE	LM-HAEM-0025 LP-HAEM-0013
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination and differential leucocyte count		Microscopy	Microscope	Standard Method	LM-HAEM-0017 LM-HAEM-0018 LP-HAEM-0004
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR)	Sodium Citrate/EDTA	Sedimentation	Westegren (Manual)	CE based on standard method	LM-HAEM-0011
1030 Haematology - .05 Automated differential leucocyte counts	Full Blood Count with automated differential leucocyte count	EDTA Blood	Automated Electrical Impedance VCS technology Calculations	Beckman Coulter Unicel DxH 800	CE	LM-HAEM-0025 LP-HAEM-0013
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites		Staining/ Microscopy/ Calculation/ Chromatographic Kit	Microscope	CE	LM-HAEM-0010 LM-HAEM-0012
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT)/APTT Ratio	Sodium Citrate	Coagulometric / Calculation	APTT 16.0 - 400.0 /ACL Top 550	CE IVDR	"LM-HAEM-0026, LP-HAEM-0016 ICSH recommendations for processing of blood

						samples for coagulation testing "
	Clauss Fibrinogen (FIB)		Coagulametric	0.35 - 10.0 /ACL Top 550	CE IVDR	LM-HAEM-0027, LP-HAEM-0016 ICSH recommendations for Fibrinogen Assays
	D Dimer		Enzyme Linked Fluorescence	Mini Vidas	CE	LM-HAEM-0022 LP-HAEM-0011
	Prothrombin Time/ INR (PT/INR)		Coagulametric / Calculation	PT 8.0 - 320.0 /ACL Top 550	CE IVDR	LM-HAEM-0026, LP-HAEM-0016 ICSH recommendations for processing of blood samples for coagulation testing
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen	EDTA Blood Plasma	Manual Immunoassay	Clearview IM II Kit	CE	LM-HAEM-0016

## Blackrock Clinic Laboratory

### Microbiology and Virology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1011 Macroscopic examination and description	Macroscopic examination and description of specimens	Sputum, CSF, Faeces, Sterile fluids	Manual/ Macroscopic examination and description of specimens	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO- 0025 LM-MICRO-0026 LM-MICRO- 0032 LM-MICRO- 0081 LM-MICRO- 0031
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Microscopic examination of General Bacteriology	All swabs BAL Respiratory Specimens CSF CAPD Fluids Faeces Colonic Aspirates Fluids Corneal Scrapings Tissues Biopsies Artificial devices Urine	Microscope/ Microscopic examination with or without fixation and staining with dyes for enumeration and description of bacteria	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0012
1012 Preparation of films on glass slides followed by microscopic examination	Microscopic examination for Fungi	Urine Liver and spleen aspirates	Microscope/ Microscopic examination with or	Based on Standard Method	N/A	Public Health England (PHE) - UK standards

with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi		Sputum Bile CSF Skin Hair Nail	without fixation and staining with dyes for enumeration and description of fungi			for Microbiology LM-MICRO-0008
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of general bacteria	Aqueous/Vitreous fluids Corneal Scrapings	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0029
		Artificial devices	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0045
		Aspirates	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0032 LM-MICRO-0022
		Axilla swab	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0038 LM-MICRO-0042 LM-MICRO-0040
		BAL	Manual/ Manual culture in agar based media with incubation of	Based on Standard Method	N/A	Public Health England (PHE) - UK standards

		specimens at defined temperatures for defined periods. Visual observation of growth.			for Microbiology LM-MICRO-0025
	CAPD Fluid	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0027
	Cerebrospinal Fluid	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0026
	Ear Swab	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0028
	Eye swabs Conjunctival swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0029
	Faeces Colonic aspirates	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0031

		defined periods. Visual observation of growth.		
Fluids	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0032
High Vaginal Swabs Endocervical Swabs Cervical swabs Urethral swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0058
Mouth Swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0037
Nasal Swab Groin Swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0038 LM-MICRO-0042 LM-MICRO-0040
Pharyngeal swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0044

	Pus	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0022
	Rectal swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0043 LM-MICRO-0087
	Respiratory Specimens	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0025
	Skin	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0040
	Throat swab	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0044
	Tips	Manual/ Manual culture in agar based media	Based on Standard Method	N/A	Public Health England (PHE) - UK standards

			with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.			for Microbiology LM-MICRO-0036
	Tissue		Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0045
	Urine Suprapubic Aspirate		Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0046
	Wound swabs		Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0022 LM-MICRO-0040
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of fungi	CSF	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0026
		Skin Hair Nail	Manual/ Manual culture in agar based media with incubation of specimens at defined	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0033

			temperatures for defined periods. Visual observation of growth.			
	Sputum		Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0025
	Urine		Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0046
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Clostridium Difficile	Faeces	TechLab C.Diff Quik Chek Complete Kit/ Enzyme Immunoassay	CE	N/A	LM-MICRO-0081
	Legionella Pneumophilia Antigen	Urine	BINAX Legionella Urinary Antigen Kit/ Enzyme Immunoassay	CE	N/A	LM-MICRO-0073
	Streptococcus Pneumonia Urinary Antigen		BINAX Streptococcus pneumoniae Urinary Antigen Kit/ Enzyme Immunoassay	CE	N/A	LM-MICRO-0074
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04	Detection of OXA-48, KPC, NDM, VIM and IMP Carbapenemases in bacterial culture	Bacterial Isolate	O.K.N.V.I RESIST-5 Kit CORIS BioConcept	CE	N/A	LM-MICRO-0093

Immunochromatographic methods,	MRSA Confirmation Testing		PBP2a SA Culture Colony Test Alere Kit	CE/ Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0097
			Cepheid Gene Xpert/ RT-PCR	CE	N/A	LM-MICRO-0095
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Detection of Carbapenemases Using the Xpert® Carba-R Assay		Cepheid Gene Xpert/ RT-PCR	CE	N/A	LM-MICRO-0081
	Detection of toxin producing C. difficile using the Xpert® C. difficile BT Assay	Faeces	Cepheid Gene Xpert/ RT-PCR	CE	N/A	LM-MICRO-0081
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of Organisms	Bacterial and Fungal Isolates	Identification using manual and automated systems/ Kits/tests and automated Vitek 2	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0017 LP-MICRO-0021 LP-MICRO-0022 LP-MICRO-0026 LP-MICRO-0031
			MALDI-TOF/ Mass Spectrometry	CE	N/A	LP-MICRO-0026
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly	E Test	Bacterial isolates	Based on Standard Method	CE	N/A	LM-MICRO-0003 Public Health England (PHE) - UK standards for Microbiology

growing aerobes) - .01 Anaerobes						
	Manual Disc diffusion		Based on Standard Method	CE	N/A	LM-MICRO-0060 Public Health England (PHE) - UK standards for Microbiology
	Measurement of Antimicrobial activity in Aerobic and Anerobic bacteria and application of clinical interpretive criteria		Automated MIC methodology using Vitek 2 system	CE	N/A	Public Health England (PHE) - UK standards for Microbiology Investigations LP-MICRO-0031 LP-MICRO-0022 LM-MICRO-0060